## REMARKS

In the Office Action mailed from the United States Patent and Trademark Office on March 3, 2009, claims 1-9 were rejected under 35 U.S.C. 112, first paragraph; claims 7-9 were rejected under 35 U.S.C. 112, second paragraph; claims 1-2 and 7-9 were rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 5,250,035 to Smith et al. ("Smith") in view of U.S. Patent Publication No. 2002/0123723 to Sorenson et al. ("Sorenson"); and claims 3-6 were rejected under 35 U.S.C. 103(a) as being unpatentable over Smith et al. and Sorenson in further view of U.S. Patent Publication No. 2002/055715 to Young et al. ("Young").

**Rejections under 35 U.S.C. 112**

Claims 1-9 were rejected under 35 U.S.C. 112, first paragraph. In particular, the pending Action indicates that the recitation for "thirteen fenestrations" and "within three centimeters of the distal end" lack support in the as-filed specification. Independent claims 1, 5, and 7 each have been amended to recite "a plurality of fenestrations isolated to within 0.17 inches of the distal end of said hollow needle," which finds support in the originally filed specification, page 8, lines 7-17. Accordingly, Applicant respectfully requests that the § 112, first paragraph rejection be withdrawn at this time.

Claims 7-9 were rejected under 35 U.S.C. 112, second paragraph. In particular, the pending Action indicated that the recitation of "said fenestrated needle" in line 6 of claim 12, line 1 of claim 8 and lines 2-3 of claim 9 lack sufficient antecedent basis in the claims. Applicant has amended the recitation "said fenestrated needle" in line 6 of claim 7 to read "a fenestrated needle" providing sufficient antecedent basis for the remaining recitations for "said fenestrated needle" in claim 7, in line 1 of claim 8 and lines 2-3 of claim 9. Accordingly, Applicant respectfully requests that the 35 U.S.C. § 112, second paragraph rejections be withdrawn at this time.

**Rejections under 35 U.S.C. 103**

Claims 1, 2 and 7-9 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No 5,250,035 ("Smith") in view of U.S. Patent Publication No. 2002/0123723 ("Sorenson"). Applicant respectfully submits that the cited references, alone or in combination, do not teach or suggest all the limitations recited in the claim set provided herein. In particular independent claims 1, 5 and 7 contain limitations drawn to a hollow needle having a plurality of fenestrations longitudinally isolated to within 0.17 inches of the distal end of said hollow needle. The new limitations find direct support in the as-filed specification, page 7, lines 12-22. The isolation of a plurality of fenestrations to within 0.17 inches of the distal end of a needle provides the unexpected benefit of allowing a method for properly locating and anesthetizing a fascial compartment containing a nerve while avoiding intravascular injection and/or inadvertent penetration of the affected nerve. Smith's disclosure related to a spinal catheter and Sorensen's disclosure related to a method for diffusing medication in a subcutaneous injection fail to read on the peripheral nerve block needle of the present application.

The pending Action indicates that Smith fails to teach a plurality of fenestrations disposed near the distal end of a needle and relies on the teachings of Sorensen to teach a plurality of fenestrations located proximate to a distal end of a needle. In particular, the pending Action relies on the language "the distal discharge portions 50 may extend any suitable predetermined length from the distal end 45 toward the proximal end 42 of the tubular element 25" from paragraph 27 of Sorensen to teach a plurality of fenestrations isolated to within 0.17 inches from the distal end of a needle. Given only this limited language in Sorensen, one skilled in the art would not have been motivated to design the needle of the present invention, which requires that a plurality of fenestrations being longitudinally isolated to within 0.17 inches of the distal end of the hollow needle. The conclusary assertion that the language cited from paragraph 27 of Sorensen includes the claim limitation of "within 0.17 inches of the distal end" lacks support both in Sorensen and in the art in general.

Sorensen disclosed a method of administering medicine along nearly the entire length of a needle inserted into a patient, not the isolation of a plurality of fenestrations to within 0.17 inches from the distal end of a needle. Sorensen's needle and system were primarily developed for the purpose of providing uniform dispersion of medication, "it provides a particularly useful application for uniform dispersion of medication to perfuse a treatment [...]" Sorensen, paragraph 2. Sorensen's needle, in fact, was developed to address the "need [remaining] for an efficient means of introducing medication to a treatment site of a size larger than the absorption field immediately surrounding the discharge orifice of a needle or catheter." Sorensen, paragraph 11.

In accord with the problem sought to be solved by Sorensen in the development of the disclosed needle, each of the figures submitted in association with Sorensen's application disclose needles with perforations that extend along almost the entire length of the needle. In accord with the embodiments depicted in Sorensen's figures, the specification provided by Sorensen likewise discloses an apparatus for subcutaneous diffusion and dispersion of medication along the tubular elements length. Sorensen, abstract. Sorensen indicates that the tubular element includes a plurality of perforations formed through the wall of the tubular element for the purpose of providing substantial uniform volume metric discharge of therapeutic fluids injected through the lumin and into the treatment zone inside a patient because such discharge more uniformly dispersed medication to a treatment zone inside a patient compared to a point source fluid introduction. Sorensen, paragraph 33. Sorensen indicates that the resulting treatment zone has a size larger than the absorption field immediately surrounding the single discharge orifice of a needle or a catheter. Sorensen, paragraph 33. Accordingly, Sorensen specifically differentiates itself from "point-source" fluid introduction of prior art devices. One skilled in the art, motivated to design a peripheral nerve block needle would not view Sorensen's disclosure related to subcutaneous diffusion and dispersion of medication as analogous art.

In contrast to the broad, uniform release strategy of Sorensen, the present invention focuses on precisely placing its injections in order to avoid intravascular injections and/or inadvertent penetration of a nerve. Specification, page 3, lines 20-22. Because the space in a

fascial convenient is very small and located proximate a nerve, exact administration of medicine is required. It would be dangerous to apply Sorensen's teachings of diffusion and dispersion to the present invention, as application of Sorenson's invention would send anesthetic outside the boundaries of the well defined fascial compartments in which Applicant directs the anesthetic. The importance of localizing the fenestrations near the distal end of the needle is elucidated in a non-limiting example found on page 8 of the specification, which indicates that "fenestrations are preferably located within one or two millimeters, and most preferably within 0.17 inches of each other for this purpose," wherein said purpose is to administer analgesic to a discrete fascial compartment of only a few millimeters width, "[f]or example a discrete compartment of only a few millimeters is located between the semitendinosis muscle 32 and bicep femoris muscle 34. This facial compartment 30 houses the sciatic nerve 36, one of two major lower extremity nerves. Fenestrations 20 are spaced at relatively small intervals along the needle 12 in order to maximize an even distribution of local anesthetic to any particular fascial compartment 30, including particularly narrow compartments such as the housing of the sciatic nerve 36." Specification, pg. 8, lns. 7-17. Use of Sorenson's needle and its release of drugs along the entire length of the needle produces a dangerous situation if utilized to administer drugs to block peripheral nerves as claimed by the present application. Because the combination of art does not teach every limitation of the claimed invention, Applicant respectfully requests that the Examiner withdraw his Section 103 rejection.

## CONCLUSION

If any impediments to the allowance of this application for patent remain after the above amendments and remarks are entered, the Examiner is invited to initiate a telephone conference with the undersigned attorney of record.

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Respectfully submitted,

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